

PSJ1 Exh 7

From: Chunderlik, George
Sent: Thu, 14 Apr 2016 18:03:10 -0400
To: Hart, Erin
Subject: RE: USL Questionnaire
Attachments: Controlled Substance Handling Questionnaire_Upsher Smith.doc

Hi Erin,

Here is the completed questionnaire.

I marked NO for the question that asked if we would be willing to send a copy of our documented SOM business practice. They may balk at that.

Thanks,
George

From: Hart, Erin
Sent: Wednesday, April 13, 2016 9:58 AM
To: Chunderlik, George <George.Chunderlik@gianteagle.com>
Subject: USL Questionnaire

Hi George – can you help fill in any blanks?

Thanks!

Erin Hart | Merchandising Manager - Pharmacy | Giant Eagle, Inc.
☎: 412.968.5157 | ✉:erin.hart@gianteagle.com



April 14, 2016

Company:

Contact:

Re: Controlled Substance Handling

Dear Trusted Business Partner:

In this time of heightened scrutiny of the pharmaceutical supply chain, it is imperative that we work together with our business partners to ensure that the products that reach our ultimate customers are authentic and that they have the quality, potency and purity that our customers expect.

As a result, Upsher-Smith is conducting a formal written partner survey to better understand your organization's processes specific to handling of controlled substances. We would appreciate a few minutes of your time to complete this brief questionnaire and to certify the accuracy of your responses for our records. It is important to note that any information shared with Upsher-Smith will be kept, as expected, confidential and used for internal purposes only. It will not be shared with others, including government regulators, outside our organization.

Thank you for your attention and for providing this critical information.

Nancy L. Van Gieson

Vice President, Quality and Corporate Compliance/Chief Compliance Officer



Controlled Substance Handling Questionnaire

General Instructions: You will receive this questionnaire in one of two ways: hard copy using the United States Postal Service or electronic copy via email. If you receive a hard copy of the questionnaire, please complete, sign, and return the questionnaire by mail in the enclosed self-addressed stamped envelope. If you receive this questionnaire via email, the intent is that it be completed on-line, printed and signed. However, you may print and complete it manually, then forward the signed questionnaire via email to customerservice@upsheer-smith.com.

We request this questionnaire be completed by the person (or persons) within your organization responsible for oversight of your controlled substance practices. Please check your response, where applicable, and provide a detailed response, where requested. Please return the completed questionnaire and any supporting documentation.

Company Organization and Capabilities:

1. DEA Registration Number: RG0491047
Registration Business Activity: Distributor
2. Who is directly responsible for managing the handling of controlled substances?

Name: Christy Hart
Title: Supervisor
Department: Pharmacy Inventory Systems

3. Who is responsible for signing DEA Form 222s for Schedule II controlled substances?

Name: Erin Hart
Title: Merchandising Manager
Department: Pharmacy Purchasing

General Controlled Substance Handling:

1. Do the areas used to store controlled substance products comply with all applicable DEA requirements?

Yes ☒ No ☐

If NO, please provide a brief explanation.



2. Describe who within your organization has access to the controlled substance areas. Operations Manager; Inventory Supervisor, Loss Prevention
3. Do you currently have a controlled substance procedure governing the receipt, storage, handling and distribution of controlled substances that is consistent with, and compliant to DEA regulations, 21CFR part 1300 to End?

Yes ☒No ☐

If NO, please provide a brief explanation.

4. Has the facility/process for handling controlled substance products been inspected by the United States Drug Enforcement Administration?

Yes ☒No ☐

Last inspection date (MM/YYYY):

November 2015

Suspicious Order Monitoring (SOM):

1. Do you currently have an active and documented SOM process?

Yes ☒No ☐

If YES, how long has your documented process existed?

0 - 6 months ☐6 - 18 months ☐18+ months ☒

If NO, are there plans in place to develop and implement a process?

Yes ☐No ☐

Anticipated date for process implementation:

2. Does your current process include monitoring your individual customers based on the following criteria:

Order Quantity Yes ☒No ☐Order Frequency Yes ☒No ☐Order Pattern Yes ☒No ☐

3. Is your suspicious order monitoring process automated?

Yes ☒No ☐

4. Please briefly describe how technology is used in the SOM process.
The ordering monitor system uses algorithms to identify controlled substance orders that require investigation before releasing the order for distribution.

5. Would you be willing to send a copy of your documented SOM business practice to USL?

Yes ☐No ☒

6. Please provide additional information or details on how you use frequency, pattern, quantity or other criteria to establish definitions or characterizations for suspicious orders.

The order monitoring system generates flags based on quantity of product ordered and characteristics specific to pharmacy location, chemical, Generic Product Identifier, NDC number, and order patterns.

7. Briefly describe the investigative process you would follow if an order is deemed suspicious.

The investigative process includes review of:

- Store Purchasing patterns
- Store Dispensing patterns
 - Percentage controlled substance prescriptions dispensed
- Form of payment
 - Third party
 - Cash
- Individual prescriptions for controlled substances
- Prescriber histories and patterns
- Interviews with store pharmacists and technicians
- Interviews with the Pharmacy District Leader

8. Once a customer has an order on file that was deemed suspicious, do you monitor this customer more closely for a certain period of time?

Yes ☒No ☐



If Yes, how long do you monitor the customer more closely?

- Less than 6 months ☐
6 to 12 months ☒
12 months ☐
If more than 12 months, please specify:

Thank you for taking the time to complete this questionnaire. Your feedback will assist us in continuing to provide excellent customer service in a timely manner, while protecting the pharmaceutical supply chain. Please contact Carol Staffenhagen (763-315-2695) or Karen Kartes (303-607-4493) if you require assistance completing the survey.

If the questionnaire is completed on-line, please print, sign, date and return to USL Customer Service by email to customerservice@upsher-smith.com. You may also print, sign, and return the questionnaire by mail to:

Upsher-Smith Laboratories, Inc.
Attn: Customer Service
6701 Evenstad Drive
Maple Grove, MN 55369-6026

I certify that the information provided is accurate to the best of my knowledge by signing below.

Print Name / Job Title

Signature / Date

Confidential

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